CFR 1700.1(b)(2)), the term *household substance* is defined as ''any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household * * *.'' The Commission has issued requirements for special packaging for certain hazardous substances at 16 CFR 1700.14(a). Unless otherwise indicated in the requirements for specific hazardous substances, the Commission interprets the term ''household substance'' as only applying to these hazardous substances when packaged in containers with a capacity of less than 5 gallons. As a result, unless otherwise specified, the hazardous substances at 16 CFR 1700.14(a) are not required to be in special packaging when packaged in containers of 5 gallons or more.

(Secs. 2, 5, 7, 9, Pub. L. 91–601; 94 Stat. 1670–1674 (15 U.S.C. 1471, 1474, 1476, 1478); sec. 30(a), Pub. L. 92–573, 86 Stat. 1231 (15 U.S.C. 2079(a))

[43 FR 53712, Nov. 17, 1978]

PART 1702—PETITIONS FOR EXEMPTIONS FROM POISON PREVENTION PACKAGING ACT REQUIREMENTS; PETITION PROCEDURES AND REQUIREMENTS

Sec.

AUTHORITY: 15 U.S.C. 1471(4), 1472, 1474, 1269(a), 2079(a); 21 U.S.C. 371(a).

SOURCE: 45 FR 13064, Feb. 28, 1980, unless otherwise noted.

§ 1702.1 Purpose and policy.

(a) Section 1700.14(a) of part 1700 lists household substances the Consumer Product Safety Commission requires, under section 3(a)(1) of the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1472, to be contained in special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances. There may be occasions, however, when the Commission determines that a particular substance should be exempt from special packaging requirements.

(b) The Commission may, either on its own initiative or upon the petition of any interested person, amend the regulation at §1700.14(a) by exempting a substance or category of substances from special packaging requirements. The purpose of these rules is to provide procedures and requirements for submitting petitions for exemption from special packaging requirements.

§ 1702.2 Procedural requirements and recommendations.

(a) *Requirements.* To be considered a petition for exemption from special packaging requirements under this part a document filed under this part must:

(1) Be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814,

(2) Be written in the English language,

(3) Contain the name and address of the petitioner,

(4) Contain an explicit request for exemption from special packaging requirements,

(5) Identify the category of substances under §1700.14(a) from which the exemption is sought, and

(6) Identify the particular substance for which the exemption is sought.

(b) *Failure to meet requirements.* Where a submission fails to meet all of the requirements of paragraph (a) of this section, the Office of the Secretary shall notify the person submitting it, describe the deficiency, and explain that the petition may be resubmitted when the deficiency is corrected.

(c) *Procedural recommendations.* The following are procedural recommendations to help the Commission in its consideration of petitions. The Commission requests, but does not require, that petitions filed under this part:

(1) Be typewritten,

(2) Include the word ''petition'' in a heading preceding the text,

(3) Include the telephone number of the petitioner, and

(4) Be accompanied by at least five (5) copies of the petition.

[45 FR 13064, Feb. 28, 1980, as amended at 62 FR 46668, Sept. 4, 1997]

§ 1702.3 Substantive requirements.

(a) A petition filed under this part shall include the information required by this part, or a satisfactory explanation for the absence of the information. As provided by §1702.4, a petition which is not complete may be closed. To be considered complete, a petition shall include the following:

(1) A statement of the justification for the exemption in accordance with §1702.7,

(2) All reasonably available human experience data, reasonably available relevant experimental data (both human and animal), product and packaging specifications, labeling, and marketing history, in accordance with §§1702.8 through 1702.14,

(b) As used in this regulation, ''reasonably available'' information is data in the petitioner's possession; data that has previously been generated by the petitioner, and data that is obtainable from such sources as: Reports from Poison Control Centers; reports of adverse reactions that have been submitted to the petitioner; the medical, pharmacological, and toxicological literature; and information required by the FDA for an Investigational Exemption for a New Drug (IND) or a New Drug Application (NDA).

§ 1702.4 Petitions with insufficient or incomplete information.

If a petition is submitted that is not complete and does not explain the reason for the absence of the information, the Commission shall afford the petitioner a reasonable opportunity to provide additional information. If the required information is not submitted to the Commission, or if the petitioner does not satisfactorily explain the absence of the information within a reasonable time, the petition shall be closed if insufficient or incomplete information has been submitted to enable the Commission to evaluate the merits of the exemption request.

§ 1702.5 Failure to supply adverse information.

Failure to obtain and provide the Commission with all reasonably available information that the petitioner knows is unfavorable or could reasonably expect to be unfavorable to the petition shall result in the denial of the petition.

§ 1702.6 Trade secrets and other confidential information.

Where a petition contains material that the petitioner believes should be exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. 552, the petitioner shall comply with the requirements of 16 CFR part 1015, the Commission's regulation under the Freedom of Information Act concerning requests for treatment as exempt material. The Commission shall act upon any request for treatment as exempt material in accordance with the provisions of 16 CFR part 1015.

§ 1702.7 Justification for the exemption.

The justification for the exemption, required under §1702.3, shall explain the reason for the exemption based on one or more of the following grounds:

(a) If the justification is based on a lack of need for special packaging to protect young children from serious injury or illness from the substance, the justification shall state how the lack of toxicity and lack of adverse human experience for the substance clearly supports granting the exemption.

(b) If the exemption is requested because special packaging is not technologically feasible, practicable, or appropriate for the substance, the justification shall explain why.

(c) If the exemption is requested because special packaging is incompatible with the particular substance, the justification shall explain why.

§ 1702.8 Human experience data.

Human experience data constitutes the primary criterion used by the Commission in evaluating petitions for exemptions. Petitions shall therefore include a compilation of all reasonably available reports pertaining to human use of the particular substance, including the product brand as well as generic equivalents and involving adverse reports of personal injury, illness, and significant allergenicity. Such information in children is of particular importance in evaluating exemption requests. However, similar data in adults shall also be submitted if available. Human experience data may be obtained from such sources as:

(a) Reports from Poison Control Centers,

(b) Reports of adverse reactions relative to the product that have been submitted to the company by physicians, hospitals, consumers, and other sources,

(c) Extensive searches of the medical, pharmacological, and toxicological literature, and

(d) For drugs, where the human experience data submitted is based on data required by FDA to be compiled for an Investigational Exemption for a New Drug (IND), 21 CFR part 312, or a New Drug Application (NDA), 21 CFR part 314, a summary of the relevant data should be provided. The entire NDA and IND material need not be submitted.

§ 1702.9 Relevant experimental data.

Experimental data are generated in both animals and humans in controlled situations in order to evaluate the biological effects of a substance. Certain toxicological effects cannot generally be evaluated in human beings. This is especially true of those substances which are not normally intended to be used in or on the human body or animal body. Therefore, the Commission considers experimental data obtained in animal studies to be an important supplement to such data as may exist from any experimental studies conducted in humans. The minimum toxicological evaluation necessary for a particular household substance is proportional to the expected exposure of man to that substance. Household substances which are not expected, in normal use, to contact man are subject to less extensive studies than those substances, such as drugs, which are designed to be used in or on man. The Commission has, therefore, separated the requirements of this section into three subsections. Section 1702.9(a) lists minimum acute animal toxicity data which shall be submitted, if reasonably available, for all petitions; §1702.9(b) lists those additional data which shall be submitted, if reasonably available, for drug products and all other household substances which are normally intended to be used in or on the human body; and §1702.9(c) lists those additional data which shall be submitted, if reasonably available, by petitioners requesting exemption for substances not intended for use in or on the human or animal body. The Commission emphasizes that, while not absolutely necessary, the types of data outlined in §1702.9(c) may greatly expedite the Commission's evaluation of a particular exemption request.

(a) *General criteria applicable to all petitions.* (1) Each petition for an exemption under this part shall include all reasonably available relevant experimental data relating to the petition regardless of whether such data are unfavorable to the petitioner's request. As used in this part, the term ''relevant experimental data'' includes, but is not limited to, all data, including animal and human studies revealing the nature and degree of the hazard associated with the particular substance. Generally, the hazard associated with the particular substance involves the risk of injury arising from the acute accidental ingestion of a product. Where a hazard different from the risk of injury arising from accidental ingestion is known to exist (e.g., potential for significant allergenicity, dermal or opthalmic injury from handling or

using the product), the petitioner shall also submit all reasonably available relevant experimental data evaluating the nature and degree of any additional hazard(s).

(2) All animal studies submitted in support of exemption requests should be performed in conformity with good pharmacological and toxicological practice which includes, as a minimum, complete descriptions of protocols used in experimental animal studies, and signed laboratory reports which include the following basic information:

(i) An exact description of materials tested;

(ii) A description of test animals employed in studies, including number, age, weight, sex and nutritional state of animals;

(iii) Dosage level(s) and number of animals tested per dosage level;

(iv) Basis upon which dosage was administered (e.g., as salt or base);

(v) Route of administration and dosage volume; and

(vi) Appendices containing all raw data and any additional data generated subsequent to the completion of the original study (e.g., results of histopathological examinations, if performed).

(3) Each petition shall include all reasonably available reports of Median Lethal Dosage (LD50) studies and shall include all raw data obtained in such studies. These studies should normally be conducted in both adult and weanling animals of the same species. The oral route of administration should be followed for studies involving substances subject to regulations promulgated under the Poison Prevention Packaging Act of 1970. Where a percutaneous toxicity hazard exists, the petition shall include reasonably available studies using the percutaneous route of administration. Sufficient dosage levels as well as adequate numbers of test animals per dosage level should be used to give statistical reliability to determined LD50 values.

(4) In view of the fact that LD50 values in themselves do not necessarily reflect a true estimate of the overall toxic potential of a substance, LD50 determinations should, where an LD50 value may be calculated, include:

(i) The LD50 value with 95 percent confidence limits;

(ii) A slope determination for the dose response curve, including 95 percent confidence limits; and

(iii) A description of the statistical method employed in the analysis of such data (with proper citation) as well as the statistical analysis itself.

(5) The Commission shall disregard any data which do not fulfill the strict requirements of the statistical method used in their analyses. Modifications of accepted statistical methods which have been published in the literature are acceptable to the Commission provided that a copy of the published work is submitted.

(6) Acute toxicity studies submitted with petitions should have at least a seven day observation period of test animals. Good pharmacological practice provides that test animals are observed closely for several hours following test substance administration and less frequently on subsequent test days. Succumbing animals should be necropsied as soon as practicable following death, while surviving animals should be necropsied, and gross pathological alterations noted, at the end of the observation period. Documentation of non-lethal effects occurring during these observation periods should be submitted in conjunction with acute toxicity laboratory reports. Documentation of any lethal effects occurring at high dosage levels, including mode of death (e.g., cardiac arrest/respiratory arrest), and time of death should be submitted in conjunction with acute toxicity laboratory reports. Reports of gross necropsies performed upon surviving animals should be submitted, as well as results of necropsies performed upon animals succumbing to the test substance, provided that such animals are examined prior to the onset of autolysis. Results of microscopic examinations, when indicated by the nature or results of an acute toxicity study, shall also be submitted.

(b) *Additional data criteria for petitions involving substances normally used in or on the human or animal body.* (1) Petitioners submitting exemption requests for substances normally used on or

taken into the human body or animal body shall, in addition to the requirements of paragraph (a) of this section submit the following data, where reasonably available:

(i) Summary laboratory reports of data obtained in subacute and chronic animal studies where the data pertain to the absorption, distribution, metabolism and excretion of substances in question;

(ii) A median lethal dosage (LD50) determination conducted in one additional species. Of the two LD50 determinations required for persons submitting exemption requests under this part, one should be conducted in a nonrodent species;

(iii) Summary reports of data obtained in human studies designed to measure the absorption, distribution, metabolism, and excretion of substances in question; and

(iv) Data indicating, insofar as is known, the mechanism of action of the substance in question and the mechanism by which expected toxicological effects occur. If these mechanisms are unknown, the petition should state this.

(2) Petitioners submitting exemption requests for substances normally used on or taken into the human or animal body shall, in addition to the requirements of paragraphs (a) and (b)(1) of this section, submit an evaluation of the pharmacology and toxicology of the substance in question based on reasonably available medical and scientific literature. The evaluation should be a comprehensive one, and should include proper literature citations. To the extent possible, information submitted by the petitioner justifying an exemption based on the medical and scientific literature will be evaluated under the criteria specified in §1702.9(a) for evaluating experimental data. In certain cases where the experimental data specified by §1702.9 (a) and (b) are unavailable, the medical and scientific literature may justify granting an exemption, particularly where the pharmacology and toxicology of the substance is well documented in the literature.

(c) *Optional data criteria for petitions involving substances not used in or on the human or animal body.* The following types of data, although often not generated for household substances not normally used in or on the human or animal body, may be available to a petitioner and should, where reasonably available, be submitted.

(1) Summary laboratory reports of data obtained in subacute and chronic animal studies where such data pertain to the absorption, distribution, metabolism, and excretion of the substance in question;

(2) Results of median lethal dosage (LD50) studies conducted in additional species of animals; and

(3) Any additional experimental studies relevant to the exemption request which would provide the Commission with additional means of assessing the hazards to children of the product for which exemption is sought.

§ 1702.10 Human experimental data involving the testing of human subjects.

Any human experimental data submitted with a petition requesting an exemption under this part shall include a statement establishing that adequate measures have been taken to ensure against psychological or physical injury to the subject of the human studies. The Commission considers its regulations concerning the protection of human subjects (16 CFR part 1028) to be an example of measures that are adequate to ensure against psychological or physical injury to human subjects.

§ 1702.11 Product specifications.

Each petition for an exemption shall include:

(a) A complete quantitative formula for the product, including inert ingredients, diluents, and solvents. (Petitioners should refer to §1702.6 for information regarding trade secrets.)

(b) A listing of all physical forms or dosage forms (whichever is appropriate) in which the product is available.

§ 1702.12 Packaging specifications.

Each petition for an exemption shall include the following information for each form of the product for which an exemption is sought:

(a) A description of the packaging currently in use including the name of

the manufacturer of the package and all specifications for the package,

(b) A complete packaging description including any carton or wrapping in which the product is offered to the consumer,

(c) A description of each size in which the product is offered, including physical form, color and flavoring, and

(d) An empty sample of each type and size of package petitioned for exemption and, in the case of drugs, a designation of those packages intended to be used in dispensing the product to the consumer for household use.

§ 1702.13 Labeling and packaging samples.

Each petition for an exemption under this part shall include a sample of the label and complete packaging for each size in which each form of the product for which an exemption is sought is packaged. This shall include the immediate container labeling, any package inserts, and other carton or wrapping labeling in which the product is offered to the consumer. In the case of drugs, each petition shall be accompanied by labeling on the outer carton or wrapping in which the product is offered to the retailer, as well as samples of the promotional and advertising information for the product.

§ 1702.14 Marketing history.

Each petition for an exemption under this part shall include a statement of the marketing history of the substance for which an exemption is requested. The marketing history dates from the year in which each form of the product was introduced onto the market. The marketing history shall include the total number of units of each form or strength and package size of the product distributed since the product was introduced onto the market. In the case of prescription drugs, the average prescription size for the product should also be indicated, if known.

§ 1702.15 Petitions alleging the incompatibility of child resistant packaging with the particular substance petitioned for exemption.

(a) Where the petition for an exemption is based upon an allegation that the applicable special packaging standard is incompatible with the particular substance or would seriously and adversely compromise the utility or stability of a substance, the petitioner shall submit adequate evidence to support the allegation.

(b) If the allegation of incompatibility is based upon the fact that package choice is limited by a new drug application filed with the FDA, the petition shall state the limitation of package choice and a description of a time schedule to revise the NDA in order to allow additional package choice.

(c) If the allegation of incompatibility is based upon the fact that the shelf life of the product limits package choice, the petition shall outline the particular limitation and shall include a description of a time schedule to reestablish shelf-life data.

§ 1702.16 Petitions requesting an exemption for a drug or a new drug.

(a) Where the petition requests an exemption for a drug, as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1), the petitioner shall include those reports required to be filed under the Food and Drug Administration's Adverse Reaction Reporting Program.

(b) [Reserved]

[45 FR 13064, Feb. 28, 1980, as amended at 66 FR 40115, Aug. 2, 2001]

§ 1702.17 Granting petitions.

Where the Commission determines that reasonable grounds for an exemption are presented by the petition, the Commission shall publish, in the FEDERAL REGISTER, a proposed amendment to the listing of substances requiring special packaging under §1700.14(a). ''Reasonable grounds'' for publishing a proposed exemption are information and data sufficient to support the conclusion that:

(a) The degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance, or

(b) Special packaging is not technically feasible, practicable, or appropriate for the subject substance, or

(c) Special packaging is incompatible with the particular substance.

§ 1702.18 Denying petitions.

Where the Commission determines that reasonable grounds for an exemption are not presented by the petition, the petition shall be denied, and the petitioner notified in writing of the denial, including a brief statement of the reasons therefor.

§ 1702.19 Effect of filing petition.

The filing of a petition for exemption under this part 1702 shall not have the effect of staying the regulation from which the exemption is sought. Therefore, substances subject to special packaging standards shall be considered in violation of the law unless packaged in special packaging during the Commission's consideration of a petition.